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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/913,139	02/09/98	ZENTGRAF H	8484-029-999

EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
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PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

DATE MAILED: 09/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/913,139	Applicant(s) Zentgraf et al.
	Examiner Patrick J. Nolan	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 2, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above, claim(s) *5-10* is/are withdrawn from consideration.

5) ☒ Claim(s) *4* is/are allowed.

6) ☒ Claim(s) *1-3* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Part III DETAILED ACTION

1. This application is a 371 of PCT/DE96/00369.

2. Claims 5-10 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

The following new grounds of rejections are necessitated by the amendment filed 7-2-01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a)

3. Claims 1 and 2 are rejected under 35 U.S.C. § 103 as being unpatentable over Evans et al.,, of record, in view of U.S. Patent No. 5,840,834 (A), newly cited.

Evans et al., teaches the making of polyclonal antibodies to fusion proteins containing metal binding peptides, wherein said antibodies are made against a 3 histidine containing metal binding peptide. Evans et al., also teaches that said antibodies are useful in detecting fusion proteins containing metal-binding peptides that

have been purified by immobilized metal affinity chromatography.

The claimed invention differs from the prior art only by the recitation of antibodies which bind a metal binding protein containing 6-18 consecutive histidine residues.

However, the `834 patent teaches fusion proteins containing 6 consecutive histidine residue metal binding peptides (Table 1, in particular), wherein said fusion proteins are purified using IMAC (see column 2, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the 6 histidine metal binding peptide taught by the '834 patent for the 3 histidine metal binding peptide taught by Evans et al., because Evans et al., teaches antibodies to metal binding peptides are useful to detect fusion proteins containing said metal-binding peptides purified by IMAC. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al., in view of U.S. Patent 5,840,834 as applied to claims 1-2 above, and further in view of Sevier et al., (of record).

Evans et al., and the `834 patent have been discussed supra.

The claimed invention in claim 3 differs from the prior art teachings only by the recitation of a monoclonal antibody which binds the histidine tagged fusion protein. However, Sevier et al. (Clin Chem. 27: 1797-1806, 1981), teaches the making of monoclonal antibodies from known antigens (pg 1797, column 2, in particular) and that monoclonal antibodies are more homogenous, specific and more easily available than polyclonal antibodies (abstract, in particular).

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to produce monoclonal antibodies to the fusion protein taught by the `834 patent that binds six histidine residue containing tagged fusion proteins with the expectation that monoclonal antibodies as taught by Sevier et al., are more specific, homogenous and more easily available than polyclonal antibodies and that said monoclonal antibodies would be useful in immunodetection methods of fusion proteins containing metal binding peptides as taught by Evans et al.

5. Applicant is notified claim 4 is allowable.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded

of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
September 18, 2001